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| 27777 7590 02/04/2009 PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003 | | | | |
| | | | EXAMINER FERNANDEZ, KATHERINE L | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/567,235

Applicant(s)

COLQUHOUN, CALLUM

Examiner

KATHERINE L. FERNANDEZ

Art Unit

3768

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13, 15 and 16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13, 15 and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 February 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-4, 7-11 and 15-16 are rejected under 35 U.S.C. 102(e) as being anticipated by White et al. (US Patent No. 6,656,184).

White et al. disclose a bone screw comprising: a support having an anchor mechanism (12) for anchoring the support in a bone, at least one reference member detectable by an image guided system, the at least one reference member being attached to the support (i.e. the bone screw is made of material such as stainless steel, titanium, cobalt-chrome alloys, etc. which are known in the art to be detectable by image guided systems, such as optical/camera systems) (column 4, lines 14-18), wherein the support comprises at least one limb that is resiliently deformable (20,22) (i.e. helical spring with flat abutting surfaces (see element (20, 22), Figures 1-2)), such as but not limited to a single or double helix (column 4, lines 14-41), and is configured such that, when the anchor mechanism is disposed within the bone, at least a portion of the at least one limb extends away from the bone (see Figures 4 and 5) (column 4, lines 14-55). The compressive member is allowed to return to its relaxed state after being stressed (column 6, lines 22-43). As can be seen in Figures 1-2, the ratio of the outer

diameter of the compressive member (20) to its inner diameter is at most 3:1. The anchor mechanism comprises at least one fixation member, such as a threaded screw, for anchoring the bone screw in the bone, and a coupling member for coupling the support to the fixation member, wherein the coupling member is adjustable to allow rotation of the support about the fixation member (see Figures 3 and 5).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claim 5 rejected under 35 U.S.C. 103(a) as being unpatentable over White et al. as applied to claim 1 above, and further in view of Nassar et al. (US Patent No. 5,389,107).

As discussed above, White et al. meet the limitations of claim 1. However, White et al. do not specifically disclose that the deformable limb is made from a damped elastomer. Nassar et al. disclose a shock absorbent prosthetic hip joint, which significantly dampens the force of impact caused by walking, running or similar activities (column 1, lines 8-10). They disclose that their shock absorbent hip joint can comprise of a volumetric spring that can comprise of a plurality of resilient spherical elements composed of a suitable elastomer (column 4, lines 44-61). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the invention of

White et al. to have the resiliently deformable limb be made from a damped elastomer, as Nassar et al. teaches the use of an elastomer as a resiliently deformable material.

5. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over White et al. as applied to claim 1 above, and further in view of Lieberman (US Patent No. 6,527,774).

As discussed above, White et al. meet the limitations of claim 1. However, they do not specifically disclose that the deformable limb is made from a shape memory alloy. Lieberman discloses an apparatus for attaching fractured sections of bone in a patient's body, and which prevents relative rotation of the fractured sections of bone without damaging the sections (column 1, lines 18-24). They disclose that their apparatus comprises a bone screw having a platform for drivingly rotating the bone screw and at least two helical spikes for embedding into at least one of the first and second sections of the bone upon rotation of the platform (column 2, lines 23-43). They disclose that the bone screw and the helical spikes can be made from a shape memory alloy, which has the ability to return to a predetermined shape (column 10, lines 34-60). At the time of the invention, it would have been obvious to one of ordinary skill in the art to have the deformable limb of White et al. be made from a shape memory alloy, as taught by Lieberman et al., as shape memory materials have the ability to return to a predetermined shape.

6. Claims 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over White et al. as applied to claim 1 above, and further in view of Carson (US Pub No. 2002/0198451).

As discussed above, White et al. meet the limitations of claim 1. However, they do not specifically disclose that the reference members transmit signals or reflect signals. Carson discloses systems and processes for tracking anatomy, implements, instrumentation, trial implants, implant components and virtual constructs or references, and rendering images and data related to them in connection with orthopedic, surgical and other operations (pg. 1, paragraph [0002]). They disclose that such systems and processes allow more accurate and effective resection of bone, placement and assessment of trial implants and joint performance, and placement and assessment of performance of actual implants and joint performance (pg. 1, paragraph [0002]; pg. 2, paragraph [0012]). They disclose that their invention uses position and/or orientation tracking sensors such as infrared sensors to track the positions of body parts, surgery-related items such as implements, instrumentation, trial prosthetics, prosthetic components, etc (pgs 1-2, paragraph [0011]). They disclose that the position/orientation tracking sensors and fiducials can consist of reflective elements or can be any electromagnetic, electrostatic, light, sound, radiofrequency or other desired technique, such as an "active" fiducial (i.e. microchip, transponders) (pg. 4, paragraphs [0054]-[0055]). They further disclose that the fiducials can be implanted in the body parts or in any of the surgically related devices and may also take the form of conventional structures such as a screw driven into a bone (pg. 4, paragraph [0055]). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the invention White et al. to have the reference members transmit signals or reflect signals, as taught by Carson, as fiducials that transmit or reflect signals and are

attached to surgical items, such as a bone screw, can help a surgeon navigate the items more accurately, efficiently and with better alignment and stability during a surgical procedure (pg. 2, paragraph [0012], pg. 1, paragraph [0002]).

Response to Arguments

7. Applicant's arguments with respect to claims 1-16 have been considered but are moot in view of the new ground(s) of rejection.

In response to applicant's argument with regards to the White reference, the Examiner notes that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. With regards to claim 1, White discloses all the structural elements, including at least one reference member that is capable of being detected by an image guided system (i.e. screw is made of a material that is capable of being detected by an image guided system, such as an optical/camera imaging system, etc.). Further, as can be seen in Figures 4-5, the White's invention is configured such that, when the anchor mechanism (12) is disposed within the bone, at least a portion of the at least one limb (22) extends away from the bone.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHERINE L. FERNANDEZ whose telephone number is (571)272-1957. The examiner can normally be reached on 8:30-5, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric F Winakur/
Primary Examiner, Art Unit 3768